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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/554,266

10/25/2005

Kenneth T. Douglas

39-317

2787

23117 7590 02/19/2010
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EXAMINER

JOHANNSEN, DIANA B

ART UNIT

PAPER NUMBER

1634

MAIL DATE

DELIVERY MODE

02/19/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/554,266	Applicant(s) DOUGLAS ET AL.	
	Examiner Diana B. Johannsen	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-48 is/are pending in the application.
- 4a) Of the above claim(s) 3-6 and 47 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7-30, 33-46 and 48 is/are allowed.
- 6) ☒ Claim(s) 31 and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 July 2009 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>0709</u> . | 6) <input type="checkbox"/> Other: _____ |

FINAL ACTION

1. This action is responsive to the Amendment and Remarks/Arguments of July 17, 2009 and the corrected claim and specification amendments filed November 23, 2009 (which have been entered). Claims 1-2 have been canceled, claims 3-4, 7-8, 18-22, 24, 31, 35, 37-38, and 43-46 have been amended and claims 47-48 have been added. Claims 3-6 and 47 are now withdrawn (for the reasons given below), leaving claims 7-46 and 48 under consideration herein. Applicant's amendments and arguments have been thoroughly reviewed. Claims 7-30, 33-46, and 48 are now allowed (see below). Claims 31-32 are rejected on new grounds necessitated by applicant's amendments. Any rejections and/or objections not reiterated in this action have been withdrawn. **This action is FINAL.**

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

3. Newly submitted claim 47 and claims 3-6 as presently amended are directed to an invention that is distinct from the invention originally claimed/elected, and which is not so linked with that invention so as to form a single general inventive concept under PCT Rule 13.1, for the following reasons. It is noted that independent claim 3 (from which claims 4-6 and 47 depend) has been amended such that it is not longer directed to "a nucleic acid hybridisation assay." Rather, the claim is now directed to a "method of analysis" in which "first and second exciplex partner moieties" are assayed in a medium, wherein photoirradiation is employed and the "presence or otherwise" of an

exciplex is determined. The two partner moieties are not disclosed as being linked or associated with any other entity (i.e., the moieties do not appear to constitute labels on probes or other detection reagents), nor does any other aspect of the claim impart a relationship with hybridization. The only technical feature shared by the elected invention and the invention of claims 3-6 and 47 is the photoirradiation of exciplex partner moieties in the presence of one of the organic solvents recited in the claims. However, this technical feature is disclosed in the prior art as exemplified by Lemp et al (J. Org. Chem. 68(8):3009-3016 [March 2003]; previously cited and applied as prior art with respect to canceled claims 1-2). Accordingly, this shared technical feature cannot constitute a "special technical feature" under PCT Rule 13.2, and unity of invention is therefore lacking.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, **claims 3-6 and 47 are withdrawn from consideration** as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112, second paragraph

THE FOLLOWING ARE NEW GROUNDS OF REJECTION NECESSITATED BY APPLICANT'S AMENDMENTS:

4. Claims 31-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 31-32 as amended are indefinite over the recitation of the language “the first and second polynucleotide probes are capable of binding to the target polynucleotide sequence with the 3’ end of one probe being adjacent to the 5’ end of the other probe such that there is at least one base of the polynucleotide sequence between the adjacent 3’ and 5’ ends of the probes as bound to the target”. This claim limitation appears contradictory, on the one hand requiring probes to be adjacent/next to one another, but on the other hand apparently prohibiting this positioning of the probes (requiring a gap between the probes).

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term “adjacent” in claim 31 is used by the claim to reference probes that are later in the claims specified as being close to one another but not in fact adjacent (i.e., not next to/abutting one another, in keeping with the accepted meaning of the term “adjacent”). The term is indefinite because the specification does not clearly redefine the term. It is additionally unclear whether the claims do or do not embrace probes that are actually adjacent when hybridized to the target (such that the metes and bounds of the claims are unclear). Accordingly, clarification is required.

Allowable Subject Matter

5. Claims 7-30, 33-46, and 48 are allowed. As was indicated in the prior Office action, the prior art discloses hybridization assays in which exciplex formation is employed during detection, but does not teach or suggest the use in a hybridization assay of the organic solvents of the claims during photoirradiation, which has been shown by applicants to enhance exciplex formation in hybridization assays (see, e.g., Examples 1-3).

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is

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571/272-0744. The examiner can normally be reached on Monday-Friday, 8:30 am-2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached at 571/272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diana B. Johannsen/
Primary Examiner, Art Unit 1634